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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,238	12/31/2002	Barry J. Marshall	GC-471-US	9961

7590

03/07/2005

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/070,238	Applicant(s) MARSHALL ET AL.	
	Examiner Brian Szmaj	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-9, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 4-6 and 10-22 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Claim Objections

1. Claim 12 is objected to because of the following informalities: The claim uses a trademarked name, Teflon. The word Teflon should be replaced with "polytetrafluoroethylene", the generic term for Teflon. Appropriate correction is required.
2. Claim 23 is objected to because of the following informalities: In line 3, "sallowing" appears to be misspelled, and should be replaced with "swallowing". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 8, 9, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall (4,946,440).

Hall discloses an evertible membrane catheter and further disclose a drag material (70) for obtaining a gastrointestinal sample; a protective sheath (16) for deployment about the drag material (70) such that the drag material (70) is substantially enclosed by the protective sheath (16) upon removal from the gastrointestinal tract; the device is used for the diagnosis of pathogens; a capsule (12) for carrying the drag material (70) and the protective sheath (16); the protective sheath (16) is deployed about the drag material (70) by movement from a retracted position to an extended position; swallowing

Art Unit: 3736

a gastrointestinal sampling device comprising a drag material (70) and protective sheath (16); allowing sufficient time for the drag material (70) to obtain the sample; withdrawing the drag material (70) such that on withdrawal the protective sheath (16) encloses the drag material (70); recovering the sample for testing; and encasing a drag material (70) and protective sheath (16) in a capsule (12). See Figures 3 and 4; and Column 1, lines 7-15.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (4,946,440) as applied to claim 1 above, and further in view of Caillouette (5,425,377).

Hall, as discussed above, discloses an evertible membrane catheter but fails to disclose the drag material being comprised of cotton; and the drag material further comprises a pH indicator.

Caillouette discloses a pH measurement of body fluid and further disclose the drag material being comprised of cotton; and the drag material further comprises a pH indicator. See Column 2, lines 54-63; and Column 3, lines 27-30.

Art Unit: 3736

Since both Hall and Caillouette disclose means for obtaining samples from within the body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the disclosure of Hall to include the use of a cotton material for the drag material and a pH indicator on the drag material, as per the teachings of Caillouette, since it is well known in the art to utilize materials such as cotton as a material for obtaining a sample, as well as providing a pH indicator to indicate the pH of the environment at the sample site.

Allowable Subject Matter

7. Claims 4-6, 10-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art of Beal et al (3,528,429), Beal (3,683,890), Berman (4,735,214), Beal et al (5,738,110), Baylor (6,475,145) and Pawelee (4,481,952) all disclose swallowable capsules for obtaining gastrointestinal samples, but fail to disclose the use of a protective sheath for protecting the drag material upon removal of the device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-

Art Unit: 3736

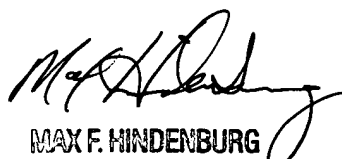
4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BS



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